

REMARKS

Claims 14 and 25 have been amended, and claims 14-26 are pending.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. REJECTIONS UNDER 35 U.S.C. § 112 ¶2

The examiner rejects claims 14-25 under 35 U.S.C. §112, ¶2, for alleged indefiniteness. As suggested by the examiner, applicants have amended the claims and believe the amendments obviate the rejection.

II. REJECTIONS UNDER 35 U.S.C. § 102(b)

The examiner rejects claims 14, 24 and 25 under 35 U.S.C. §102(b) for allegedly being anticipated by Reed *et al.* Applicants have amended the claims, as suggested by the examiner, and believe the amendments obviate the rejection.

III. REJECTIONS UNDER 35 U.S.C. § 103**A. Rejection of the Claims Over Reed et al.
in View of Sato et al. and/or Kishimoto et al.**

The examiner rejects claims 15-23 and 26 under 35 U.S.C. §103(a) as allegedly being unpatentable over Reed *et al.* in view of Sato *et al.* and/or Kishimoto *et al.* Applicants respectfully traverse the rejection.

A proper rejection for obviousness under §103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition, or device, or carry out the claimed process, and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438 (Fed. Cir. 1991). In the pending case, the examiner has failed to establish a *prima facie* case of obviousness.

In particular, the examiner has failed to provide any objective evidence of record that an artisan at the time of the invention would have been motivated to combine the cited references to obtain the claimed invention. Moreover, the examiner states that “[t]he rejection does not [assert], nor depend on, a finding that Reed administered an IL-6 antagonist.” Office Action dated February 3, 2005, pg. 4, ¶5.

So stating, the examiner effectively admits that the rejection is legally unfounded. If PYY is not an IL-6 antagonist, then Reed has no relevance to the patentability of the pending claims. In such a case, Reed merely teaches that administration of some compound is useful in treating pancreatitis and confirms that IL-6 and TNF- α are useful markers for pancreatitis. In fact, applicants previously submitted evidence (Tito *et al.* (Am. J. Surg. 165(6): 690-696 (1993)), which remains uncontested, that suggests that PYY is not an IL-6 antagonist but rather acts directly on the pancreas. As a matter of law, therefore, Reed cannot serve as the basis of an obviousness rejection under §103. Moreover no combination of the cited references yields the claimed invention.

Accordingly, the rejection should be withdrawn.

B. Rejection of the Claims Over Sato *et al.* and/or Kishimoto *et al.* in view of Gross *et al.* and Farkas *et al.*

The examiner also rejects claims 14-26 under 35 U.S.C. §103(a) as allegedly being unpatentable over Sato *et al.* and/or Kishimoto *et al.* in view of Gross *et al.* and Farkas *et al.* Applicants respectfully traverse the rejection.

As noted above, to establish a *prima facie* case of obviousness, an examiner has the burden of demonstrating that the prior art would have suggested to those of ordinary skill in the art that they should make the claimed invention and that they should do so with a reasonable expectation of success. Applicants respectfully assert that the examiner has failed to meet this burden.

In particular, the examiner has failed to show that the prior art provided the requisite expectation of success. As shown in Mukaida *et al.* (previously submitted): (1) a cytokine, such as interleukin-6, exhibits various biological actions (Pleiotropy); (2) a plurality of cytokines exhibit the same action on the same cell (Redundancy); and (3) a plurality of cytokines are involved in the same cell line depending on the process of differentiation and

growth. See English translation, pg. 5, ln. 5-17. In addition, Bellomo (previously submitted), taught that once a complicated network is activated, many cytokines belonging to the same network are produced.

Accordingly, at the time of the invention, an artisan would have expected that if an antagonist successfully blocked one cytokine, such as IL-6, another cytokine would likely compensate for the lost signal. Thus, for a given disease, such as pancreatitis, an artisan would not have reasonably expected that blocking a single cytokine would result in the prevention or amelioration of the disease. Indeed, the examiner voiced this same conclusion, noting that "the person of ordinary skill in the art would not expect that suppression of the effects of a single cytokine would completely stop or prevent a condition that is due to the effects of multiple cytokines ..." Office Action, pg. 3, ln. 6-10.

In the present case, applicants surprisingly and unexpectedly discovered that administering an IL-6 antagonist can effectively prevent or ameliorate pancreatitis. This discovery was counter to the reasonable expectations of practitioners. Accordingly, applicants respectfully request that the rejections be withdrawn.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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